

REMARKS

Further examination of claims of 1-7, 17-25, 27, 28, and 30 is reported in the present advisory action. Claims 1-7, 17-25, 27, 28, and 30 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 1-5, 17-20, 23-25, and 30 stand rejected under 35 U.S.C. § 102(b). Each of these rejections is addressed below.

Support for amendment

Amended claims 1, 17, and 30 are now, in general, directed to a nematode infected with a bacterium that increases ced programmed cell death in the nematode. Support for this amendment is found, for example, at page 14, line 13 through page 20, line 6 of the specification. No new matter has been added by this amendment.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-7, 17-25, 27, 28, and 30 stand rejected under 35 U.S.C. § 112, first paragraph as lacking an adequate written description. Claims 1-7, 17-25, 27, 28, and 30 further stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Each of these rejections is addressed below.

Written Description

Claims 1-7, 17-25, 27, 28, and 30 stand rejected under 35 U.S.C. § 112, first

paragraph as lacking an adequate written description. The Office maintains that the specification fails to adequately describe nematodes, other than *Caenorhabditis elegans* (*C. elegans*), that can be persistently infected with a bacterium. In response to applicants' assertion that the disclosure of a single species is sufficient to satisfy the written description requirement in the present case, the Office states that "[t]here is no evidence of record to suggest that [the] response [of nematodes] to infection by various bacteria is a common attribute." As evidence of this assertion, the Office cites Tan et al. (Proc. Natl. Acad. Sci. USA. 96:71-720, 1999; hereinafter "Tan") and Bottjer et al. (Amer. J. Veterin. Res. 39:151-153, 1978; hereinafter "Bottjer") for teaching examples of bacterial nematode infections that would conflict with applicants' definition of the terms "persistent infection." The Office therefore concludes that one skilled in the art would not know what *bacteria* would produce a persistent infection in what *nematode*. applicants respectfully traverse this rejection.

Applicants first point out that, contrary to the Office's assertion, neither Tan nor Bottjer provide examples that conflict with applicants' disclosure and that would lead one skilled in the art to question what is meant by the terms "persistent infection." In this regard, applicants point out that the present application specifically discloses various morphological and structural features that distinguish persistent bacterial infections from other bacterial infections including, for example, a net loss in cell numbers due to the increase in programmed cell death in the nematode.

To expedite prosecution, claims 1, 17, and 30 (from which the other rejected claims depend) have been amended to require that the bacterium increase programmed cell death in the infected nematode. Applicants' description conveys applicants' presently claimed invention to those persons of skill in the art, and it is this description that allows the skilled worker to identify and recognize other species falling within the present claims. As a result, applicants' specification clearly satisfies the written description requirement, as set forth by the case law, and applicants request reconsideration and withdrawal of this basis for the § 112 rejection.

Enablement

Claims 1-7, 17-25, 27, 28, and 30 stand rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Office maintains that the specification, while enabling for a *C. elegans* persistently infected with *S.typhimurium*, is not enabling for other nematodes and bacteria. In response to applicants' assertion that the specification provides ample enabling teachings, the Examiner relies on Tan and Bottjer to emphasize the unpredictability of the claimed invention and concludes that one skilled in the art would not have been able to practice the claimed invention in the absence of undue experimentation. Applicants respectfully traverse this rejection.

Applicants disagree with the Office's assertion that the level of predictability in the art at the time of filing was such that one skilled in the art would not have been able to

practice the claimed invention without undue experimentation. Applicants note that neither Tan nor Bottjer provide any examples of bacterial infections in nematodes that contradict applicants' teachings. Applicants therefore assert that the level or predictability was high at the time of filing and consequently, one skilled in the art would have been able to practice the claimed invention without undue experimentation.

Indeed, one skilled in the art reading the present specification would immediately recognize that, in addition to *C. elegans*, virtually any nematode and any programmed cell death-inducing bacterium may be employed according to the methods of the invention. One skilled in the art would also understand that the practice of the claimed invention would merely require standard application of routine methods, as described and exemplified in applicants' specification. Accordingly, the practice of the invention would only require one to culture a nematode in the presence of a bacterium and assay for infection, as is taught in the specification without undue experimentation. Thus, because the present specification provides guidance to those skilled in the art on how to carry out the claimed invention without undue experimentation, the § 112, first paragraph rejection should therefore be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 1-5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Tan et al. (Proc. Nat. Acad. Sci. 96:2408-2413, 1999; hereinafter “Tan”). Claims 1-5, 17-20, 23-26, and 30 also stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ausubel et al. (WO 98/50080; hereinafter “Ausubel”). For the following reasons, these rejections should be withdrawn.

To support a rejection of a claim under § 102, a single prior art reference must describe all of the elements and limitations of the rejected claim. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 1001, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991). Neither Tan nor Ausubel meet this standard in supporting a rejection of any of the claims.

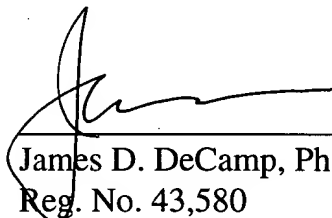
By the present amendment, applicants’ claims, in general, require a nematode which is infected with an isolated bacterium, where the bacterium increases ced programmed cell death. Neither Tan nor Ausubel teach such a nematode. Indeed, applicants’ specification (see, for example, page 14, line 13 through page 20, line 6) demonstrates that the interaction between *C. elegans*/*P. aeruginosa* does not result in increased ced programmed cell death, as required by the amended claims. In particular, *P. aeruginosa* - in contrast to *S. typhimurium* - does not increase the level of programmed cell death. This rejection should therefore be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is requested. Enclosed is a petition to extend the period for replying for five months, to and including January 21, 2005. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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James D. DeCamp, Ph.D.
Reg. No. 43,580

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045